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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Gerard M. Jensen et al.  
Title: LIPOSOMAL FORMULATIONS

Docket No.: 1992.005US1  
Filed: November 26, 2003  
Examiner: Unknown  
Serial No.: 10/723,423  
Due Date: N/A  
Group Art Unit: 1615

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

- ☒ A return postcard.
- ☒ A Supplemental Information Disclosure Statement (2 pgs.), Form 1449 (2 pgs.), and copies of 15 cited documents.

Please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
Customer Number 21186

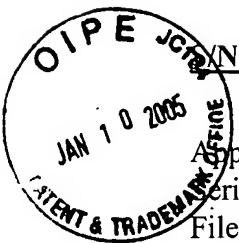
By: Monique M. Perdok Shonka  
Atty: Monique M. Perdok Shonka  
Reg. No. 42,989

**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 6 day of January, 2005.

NICOLE JACK  
Name

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Signature

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
(GENERAL)



IN 10/723,423

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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Title:	LIPOSOMAL FORMULATIONS		

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Supplemental Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Supplemental Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 19-0743 in order to have this Supplemental Information Disclosure Statement considered.

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

The present application is either a U.S. national patent application filed after June 30, 2003 or an international application that entered the national stage under 35 U.S.C. § 371 after June 30, 2003. Thus, Applicant believes that the U.S. Patent & Trademark Office has waived the requirement under 37 C.F.R. 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication. The waiver is provided in a pre-OG notice from the U.S. Patent & Trademark Office entitled "Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003" and dated July 11, 2003. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

Respectfully submitted,  
GERARD M. JENSEN ET AL.

By their Representatives,  
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Date Jan 5 2005

By Monique M. Perdok Shonka  
Monique M. Perdok Shonka  
Reg. No. 42,989

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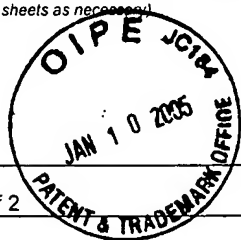
Nicole [Signature]  
Name

[Signature]  
Signature

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)



Sheet 1 of 2

Complete if Known

Application Number	10/723,423
Filing Date	November 26, 2003
First Named Inventor	Jensen, Gerard
Group Art Unit	1615
Examiner Name	Unknown

Attorney Docket No: 1992.005US1

**US PATENT DOCUMENTS**

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Filing Date If Appropriate
	US-4,145,410	03/20/1979	Sears, Barry D.	06/17/1997
	US-4,224,179	09/23/1980	Schneider, Michel	09/23/1980
	US-4,235,871	11/25/1980	Papahadjopoulos, Demetrios P., et al.	02/24/1978
	US-4,522,803	06/11/1985	Lenk, Robert P., et al.	03/24/1983
	US-4,588,578	05/13/1986	Fountain, Michael W., et al.	08/08/1983
	US-4,753,788	06/28/1988	Gamble, Ronald C.	01/31/1985
	US-4,946,683	08/07/1990	Forssen, Eric A.	08/04/1989
	US-5,077,056	12/31/1991	Bally, M. B., et al.	12/12/1988
	US-5,316,771	05/31/1994	Barenholz, Yechezkel, et al.	12/18/1992
	US-5,380,531	01/10/1995	Chakrabarti, Ajoy, et al.	06/02/1992
	US-5,795,589	08/18/1998	Mayer, Lawrence D., et al.	02/05/1997
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	T <sup>2</sup>
	EP-0546951A1	06/16/1993	Ostro, Marc J.	
	EP-0719546A1	07/03/1996	Bally, Marcel B., et al.	
	WO-03041682A3	05/22/2003	Webb, Murray, et al.	
	WO-9913816A2	03/25/1999	Moynihan, Karen L., et al.	

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ADLAKHA-HUTCHEON, G., et al., "Controlled destabilization of a liposomal drug delivery system enhances mitoxantrone antitumor activity", <u>Nature Biotechnology</u> , 17(8), (August 1999), 775-779	
		BANDAK, S., et al., "Pharmacological studies of cisplatin encapsulated in long-circulating liposomes in mouse tumor models", <u>Anticancer Drugs</u> , 10, (November 10, 1999), 911-920	
		COLBERN, C. T., et al., "Antitumor activity of Herceptin in combination with STEALTH liposomal cisplatin or nonliposomal cisplatin in a HER2 positive human breast cancer model", <u>Journal of Inorganic Biochemistry</u> , 77(1-2), (October 1999), 117-120	
		DEMARIO, M. D., et al., "A Phase I Study of Liposome-Formulated Cisplatin (SPI-77 R) Given Every 3 Weeks in Patients With Advanced Cancer", <u>Proceedings of ASCO</u> , Vol. 17, <a href="http://www.asco.org/ac/1,1003,12-002643-00_18-0031-00_19-006314,00.asp">http://www.asco.org/ac/1,1003,12-002643-00_18-0031-00_19-006314,00.asp</a> , (1998), Abstract 883	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional) <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

<b>Application Number</b>	10/723,423
<b>Filing Date</b>	November 26, 2003
<b>First Named Inventor</b>	Jensen, Gerard
<b>Group Art Unit</b>	1615
<b>Examiner Name</b>	Unknown

Sheet 2 of 2

Attorney Docket No: 1992.005US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		HARRINGTON, K. J., et al., "Phase I-II study of pegylated liposomal cisplatin (SPI-077) in patients with inoperable head and neck cancer", <u>Annals of Oncology</u> , 12(4), (April 2001),493-496	
		HONG, R L., et al., "Direct comparison of liposomal doxorubicin with or without polyethylene glycol coating in C-26 tumor-bearing mice is surface coating with polyethylene glycol beneficial?", <u>Clinical Cancer Research</u> , 5(11), (November 1999),3645-3652	
		LIM, H. J., et al., "Influence of drug release characteristics on the therapeutic activity of liposomal mitoxantrone", <u>The Journal of Pharmacology and Experimental Therapeutics</u> , 281(1), (April 1997),566-573	
		MEERUM TERWOGT, J. M., et al., "Phase I and pharmacokinetic study of SPI-77, a liposomal encapsulated dosage form of cisplatin", <u>Cancer Chemotherapy and Pharmacology</u> , 49(3), (March 2002),201-210	
		NEWMAN, M. S., et al., "Comparative pharmacokinetics, tissue distribution, and therapeutic effectiveness of cisplatin encapsulated in long-circulating, pegylated liposomes (SPI-077) in tumor-bearing mice", <u>Cancer Chemotherapy and Pharmacology</u> , 43(1), Erratum in <u>Cancer Chemotherapy and Pharmacology</u> , 43(6), 524 (attached to downloaded document),(1999),1-7	
		VEAL, G. J., et al., "A phase I study in paediatric patients to evaluate the safety and pharmacokinetics of SPI-77, a liposome encapsulated formulation of cisplatin", <u>British Journal of Cancer</u> , 84(8), (April 2001),1029-1035	
		WORKING, P. K., et al., "Comparative intravenous toxicity of cisplatin solution and cisplatin encapsulated in long-circulating, pegylated liposomes in cynomolgus monkeys", <u>Toxicological Sciences</u> , 46(1), (November 1998),155-165	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional) <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached